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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,439

06/16/2006

Silvo Zupancic

4061-33PUS

6654

27799

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10/23/2009

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NEW YORK, NY 10176

EXAMINER

WITHERSPOON, SIKARL A

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

10/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,439	Applicant(s) ZUPANCIC, SILVO	
	Examiner Sikarl A. Witherspoon	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner has considered the amendment filed by applicants on August 5, 2009, and the remarks therein. Applicants' amendment was effective in overcoming the rejection of record under 35 U.S.C. 112, second paragraph. In light of said amendment, the examiner has withdrawn the rejection under 35 U.S.C. 103(a); however, applicants' amendment has necessitated the following new rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dolitzky et al (WO 00/45658) in view of Rameshchandra et al (WO 02/050074).

The claims, as amended, are drawn to a process for preparing and acid addition salt of venlafaxine by converting a venlafaxine precursor in the presence of a salt of formic acid, wherein the molar ratio of the formic acid salt to venlafaxine precursor is 0.3-10 to 1, to venlafaxine, and then extracting venlafaxine with a water-immiscible organic solvent, and then reacting the resulting solution with an acid to prepare the acid addition salt.

Dolitzky et al teach a process for preparing venlafaxine free base by converting N,N-didesmethyl venlafaxine hydrochloride in the presence of sodium hydroxide, formic

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acid, and formaldehyde (p 7, example 2). The reference also teaches that venlafaxine hydrochloride can be produced by exposing a mixture of venlafaxine in acetone, to gaseous hydrochloric acid (p 4, lines 1-4).

The differences between Dolitzky et al and the instant claims are that the reference does not expressly teach a reaction wherein the molar ratio of formic acid salt to venlafaxine recited in the instant claims is employed, and does not expressly teach using a water-immiscible solvent for the extraction step; however, absent a showing of unexpected results, the molar ratio of formic acid salt to venlafaxine precursor is not deemed a patentable difference since a person having ordinary skill in the art would have systematically adjusted the reactant concentration in order to optimize the reaction. Regarding the use of a water immiscible solvent, Rameshchandra et al teach the preparation of venlafaxine hydrochloride by subjecting venlafaxine base to hydrogen chloride in a solvent, wherein the solvent from which the venlafaxine hydrochloride may be ethyl acetate, acetonitrile, acetone, isopropanol, methyl isobutyl ketone, and toluene (p 8).

In view of the combined reference teachings, it would have been obvious to a person having ordinary skill in the art that venlafaxine hydrochloride may be extracted using a water immiscible solvent, such as ethyl acetate or toluene. The motivation to substitute one solvent for another lies in the selection of the desired polymorphic form of the venlafaxine hydrochloride crystals that are produced. The combined reference teachings therefore renders the instant claims obvious.

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sikarl A. Witherspoon whose telephone number is 571-272-0649. The examiner can normally be reached on M-F 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sikarl A. Witherspoon/
Primary Examiner, Art Unit 1621